K102011

Premarket Notification 510(k) Summary

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
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Date: July 2010

SEP 3 2010

Proprietary Name: Eclipse Treatment Planning System

Classification Name: Medical charged-particle radiation therapy system, 21 CFR §892.5050, MUJ, Class II

Common/Usual Name: Eclipse TPS

Predicate Devices: Eclipse Treatment Planning System, K091492

Device Description: The Varian Eclipse™ Treatment Planning System (Eclipse TPS) provides software tools for planning the treatment of malignant or benign diseases with radiation. Eclipse TPS is a computer-based software device used by trained medical professionals to design and simulate radiation therapy treatments. Eclipse TPS is capable of planning treatments for external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation, (brachytherapy) treatments.

Statement of Indications for Use: The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.

Technological Characteristics: Refer to the attached Substantial Equivalence Comparison Chart.

	Predicate Device VARIAN Eclipse 8.8 (K091492)	New Device VARIAN Eclipse 10.0
1. Indication for Use	See above	See above
2. General Usage		
External beam PHOTON planning	yes	yes
External beam PHOTON inverse planning	yes	yes
External beam ELECTRON planning	yes	yes
External beam PROTON planning	yes	yes
External beam OCULAR PROTON planning	yes	yes
Internal BRACHYTHERAPY planning	yes	yes
Stereotactic Frame Localization	yes	yes
3. Supported External Beams & Accessories		
Photon beams	yes	yes
Electron beams	yes	yes
Proton beams	yes	yes
Coplanar fields	yes	yes
Non-coplanar fields	yes	yes
Multi-leaf Collimators	yes	yes
Asymmetric collimators	yes	yes
Stereotactic Cone collimators	yes	yes
Arc fields	yes	yes
Poured Blocks	yes	yes
Compensators	yes	yes
Physical wedges	yes	yes
Dynamic wedges	yes	yes
Rotating treatment couch	yes	yes
4. Supported Brachytherapy Sources & Accessories		
Plan for high dose rate afterloader	yes	yes
Manual low dose rate brachytherapy: seeds, line sources, wire	yes	yes
Applicator library	yes	yes
Needle templates	yes	yes
5. Graphical User Interface		
Multiple-instance application	yes	yes
Multiple-workspace layout	yes	yes
Graphical display/editing of field parameters	yes	yes
Beam's-Eye-View display	yes	yes
3D patient image display	yes	yes
Model for human Eye	yes	yes
SRS Localization application	yes	yes
SRS Planning application	yes	yes
Biological Optimization application	yes	yes
Biological Evaluation application	yes	yes
3D Conformal Optimization application	yes	yes

6. Image Processing		
Orthogonal image displays (3)	yes	yes
Oblique image display	yes	yes
Edge enhancement filters	yes	yes
Image smoothing filters	yes	yes
CT/MR/PET Image Registration	yes	yes
Image blending utility	yes	yes
4D image display (registration of time series of 3D images)	yes	yes
Digitally reconstructed radiographs	yes	yes
Enclosed Volume measurement	yes	yes
Stereotactic Frame Coordinate transformation	yes	yes
7. Image Segmentation		
Geometrical shapes	yes	yes
Manual editing and manipulation tools	yes	yes
Automatic /semi-automatic tools	yes	yes
Automatic/semi-automatic on-demand and post-processing tools for individual organs/structures	yes	yes
Automatic on-demand and pre-processing tools for multiple organs/structures	yes	yes
3D Automargin	yes	yes
Logical operators	yes	yes
8. Dose Calculation		
Distributed Calculation Framework	yes	yes
Photon calculation	yes	yes
Energy Range:	1 MV – 50 MV	1 MV – 50 MV
CT-based volumetric calculation	yes	yes
Non-CT based IRREG calculation	yes	yes
Convolution method	yes	yes
Combined electron/photon scatter	yes	yes
Directional heterogeneity correction	yes	yes
Treatment head modeling	yes	yes
Photon Monitor Unit calculation	yes	yes
Beam Angle Optimization (GEOS)	yes	yes
Leaf Motion Sequencing	yes	yes
Dose Dynamic Arc planning	yes	yes
Cone Dose Calculation	yes	yes
Biological optimization	yes	yes
3D Conformal Optimization	yes	yes
AcurosXB dose calculation algorithm	no	yes
Electron calculation	yes	yes
Energy Range:	1 MeV – 50 MeV	1 MeV – 50 MeV
Gaussian Pencil Beam Model	yes	yes
Electron Monte Carlo algorithm	yes	yes
Electron Monitor Unit calculation	yes	yes
Proton calculation	yes	yes

Energy Range:	50 MeV - 300 MeV	50 MeV - 300 MeV
Brachytherapy calculation	yes	yes
AAPM TG 43 compliant	yes	yes
Point Dose calculation	yes	yes
Optimization to point dose constraints	yes	yes
Geometric optimization	yes	yes
Acuros dose calculation algorithm	yes	yes
Eclipse Algorithm Application Programming Interface (EAAPI)	no	yes
9. Dose evaluation		
Dose color wash	2D, 3D	2D, 3D
Isodose levels	2D, 3D	2D, 3D
Isodose Surface	3D	3D
Reference point dose summary	yes	yes
Dose Volume Histogram plot	yes	yes
Plan summing tool	yes	yes
Plan comparison tools	yes	yes
Evaluation using biological models	yes	yes
10. Plan Output - Hardcopy		
Graphics window screen dump	yes	yes
Patient administration data	yes	yes
Plan parameters	yes	yes
Geometrical displays of plan data	yes	yes
Dose distribution	yes	yes
DVH plot	yes	yes
BEV display	yes	yes
Patient orientation	yes	yes
User Configurable hardcopy layouts	yes	yes
11. Import/Export Interfaces		
VARiS/Vision database integration	yes	yes
DICOM RT / 3.0	yes	yes
Other image formats	yes	yes
Electromagnetic Digitizer	import	import
Film Scanner	import	import
Export field coordinates to Laser System	export	export

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Official Correspondent
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

SEP 3 2010

Re: K102011
Trade/Device Name: Eclipse Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, LHN
Dated: July 15, 2010
Received: July 16, 2010

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Eclipse Treatment Planning System (TPS)

K102011

Indications for Use

SEP 3 2010

510(k) Number (if known): K102011

Device Name: Eclipse Treatment Planning System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102011